



November 24, 1999

Dockets Management Branch, (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

Re: [Docket No. 99D-4130]

Dear Ms Kahan:

Premier applauds FDA for its recent distribution of the draft guidance entitled "Guidance on Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems." We have obtained a copy of that document and offer comments and observations by means of this letter and attachments.

First, let us share with you some background information on our organization. Premier is owned by approximately 215 hospital and healthcare organizations. These healthcare organizations operate or have affiliation relationships in place with approximately 1,800 hospital and healthcare facilities across the nation. These institutions deliver approximately one-third of the nation's acute-care services.

Starting in 1973, Premier's Clinical Technology Services (CTS) division began providing shared biomedical equipment services to hospitals in North and South Carolina. Premier takes great pride in being the leader in pioneering the biomedical service industry and providing healthcare facilities an alternative to maintenance and repair services offered almost exclusively by original equipment manufacturers.

Today, CTS provides technology management services, including medical equipment repair and maintenance services, to more than 200 hospitals and healthcare systems across the United States. Our technology management programs reach across the entire spectrum of clinical and imaging equipment; from otoscopes to magnetic resonance imaging systems. Our staff of 500 field service engineers work closely with our hospitals and health systems in the management of the entire life cycle of medical equipment. We assist hospitals and other care providers with the evaluation, selection, installation, maintenance and disposal of equipment. As a service alternative, we firmly believe in providing the highest quality and level of equipment maintenance services while following the recommendations of the original equipment manufacturers (OEMs).

While your guidance document has improved the interpretation of 21CFR, Section 1020.30, we continue to have some general concerns and questions relating to specific areas of 21CFR. For example, what is the definition of "at cost not to exceed the cost of publication and distribution" as it relates to information that the manufacturer is required

99D-4130

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November 24, 1999

Page 2

to provide to assemblers, users, and others? Certain OEMs continue to charge \$15,000 per year for their diagnostic materials. Is this reasonable?

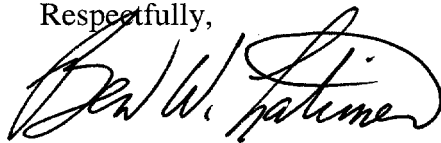
Still, other manufacturers refuse to provide any diagnostic information as it relates to assembly, installation, adjustment, and testing (AIAT). Certain OEMs remove all diagnostic materials from the hospital's premises if they are not the recognized service provider. Is this practice in compliance with 21CFR and the recently published guidance document?

We have attached a document that summarizes our view of the medical equipment maintenance industry. In addition, this document points out some of our ongoing concerns regarding 21CFR and the interpretation thereof. We ask that you take a few moments to review and consider our thoughts and observations on this issue.

Premier shares your view and concerns about protecting the public from unnecessary or dangerous electronic product radiation. We work diligently within our member institutions to lower the cost of healthcare and to support their efforts in providing the highest standards of patient care.

Premier would welcome the opportunity to meet with you at your earliest convenience to further discuss this matter. We anticipate this meeting would occur before the January 6, 2000 deadline. Mr. James L. Scott, Senior Vice President of Premier, Inc. and head of our Washington office will call your office to schedule an appointment.

Respectfully,

A handwritten signature in black ink, appearing to read "Ben W. Latimer". The signature is fluid and cursive, with a large loop at the end.

Ben W. Latimer
Vice Chairman
Premier, Inc.

attachment

cc: James L. Scott, Senior Vice President, Premier
S. Robert Doster, Senior Vice President, Premier

21 CFR Sec. 1020.30
[Docket No. 99D-4130]
Guidance on Information Disclosure by Manufacturers
to Assemblers for Diagnostic X-ray Systems

Since 1968, FDA has promulgated regulations to ensure the safety of ionizing radiation equipment, specifically x-ray equipment. During the intervening thirty-plus years, there has been much discussion as to the meaning of these regulations. Of primary importance for our ability to service these devices, is 21 CFR Part 1020--Performance Standards for Ionizing Radiation Emitting Products. Section 1020.30(g) and 1020.30(h) contains language requiring manufacturers to provide information to assemblers, users, and other persons for the purpose of ensuring safe operation of the equipment. (See appendix A.) Since this regulation contains few or no definitions of applicable non-technical words and terms, interpretation of these sections has typically revolved around exactly what information is required, to whom it must be provided, and at what cost.

On September 17, 1999, FDA released the guidance document, "Guidance on Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems." This document can be found at the FDA website, <http://www.fda.gov/cdrh/comp/2619.pdf>, and includes several important definitions of terms and concepts including:

- Assembly
- Installation
- Adjustment
- Testing

In the past these terms have been interpreted by the original equipment manufacturers (OEM's) so as to preclude providing others detailed technical information. Language in the guidance document now adequately describes what technical information is required of the OEM's, but it does not adequately describe how the information is to be transferred, the extent of the systems to be included, or the process for the industry to follow in notifying FDA of violations of this process by the OEMs.

For example, one important concept not defined is the "Certified Component." From the current language of the regulations, a certified component is a component which is "certified" by the manufacturer to meet the requirements of the regulations. Generally, this is understood to mean any replacement part, assembly, or subassembly that could affect the production of x-rays. What is FDA's position on components purchased directly from the actual parts manufacturer vs. purchasing from the OEM? What is FDA's opinion on second source parts?

New technologies have changed the way a radiation-producing device operates. Now systems can include many components not directly related to the production and control of x-rays, but which are critical to the functioning of the system. These new components

may enhance data collection, processes digital image data, and allow for electronic transmission, storage, and retrieval of this processed data. Examples are serial interfaces, laser printers, disk storage systems, and image manipulation computers and software. Unless all these newer technologies are clearly and obviously included in the definition of “component”, the patient is at risk of additional radiation exposure from repeated exams. This could potentially result in misdiagnosis and incorrect treatment of the illness or disease. If the equipment owner has no viable alternative for service other than the OEM for these components, then the equipment owner is at the mercy of the OEM for service delivery, service costs, and equipment downtime.

In addition to the new technologies, the guidance document excludes other modalities that historically have played a major role in the diagnosis and treatment of disease. Specifically, the guidance document does not address diagnostic ultrasound, nuclear medicine, or magnetic resonance imaging equipment. We emphatically believe these modalities should be given equal consideration as radiation producing devices.

Each of these modalities are used daily to diagnose patient illness and disease. Without proper equipment maintenance service, malfunctions occur, potentially leading to the misdiagnosis and inappropriate treatment of patient illness, not to mention the additional expense of repeat examinations or extended hospital stays. Each of these modalities has similar maintenance and repair requirements as radiation producing devices.

The guidance document fails to clearly define the “cost” of providing required instructional materials. The document indicates the manufacturer should provide the required materials “at a cost not to exceed the cost of publication and distribution”. We understand the manufacturer should not establish a cost that would include recovery of development costs or a profit margin. Again, we ask for more definitive clarification on “Cost”.

Under the section “Adjustment”, FDA has indicated that documentation or software programs that provide information about what needs to be done or replaced to keep a machine operating within applicable performance standards must be disclosed. This would include any required calibration references. Is the intent of this paragraph to have the assembler strictly follow the manufacturer’s suggested planned maintenance and troubleshooting procedures? If so, FDA needs to ensure that all documentation, both hardcopy and software, are made available to the assembler.

The guidance document also addresses the types of information to be provided. OEM’s are required to provide information that will allow others to maintain the equipment so that it will meet the federal requirements. The guidance document understandably allows the OEM to develop proprietary methods for increasing their efficiency and productivity. Of some concern, the guidance document does not preclude the OEM from providing to others information, methods, or software that could unnecessarily decrease efficiency or productivity. Some OEM’s have already demonstrated the capacity to go to great lengths

to inhibit others working on their products, so as unlikely as this may seem, it must be considered a real possibility.

The guidance document is also vague with regard to the type of media to be used in the distribution of the information. Though the document draws attention to the OEM's obligation to provide assembly, installation, adjustment, and testing (AIAT) software to others, and offers acceptable alternatives, it also contains this disclaimer:

"Manufacturers may also satisfy the performance standard by providing printed materials, or by any other means that results in the provision of adequate, complete, and useable instructional materials."

One can easily imagine the disruption to the equipment owner if the OEM provided only a written procedure as the technically "...adequate, complete, and useable instructional materials" in lieu of basic computer software. What could take the OEM a matter of minutes or hours with a basic level of software, could take hours or days for someone with only a written document and manual labor. Clearly some basic level of equivalence needs to be established with a further definition of the phrase, "... adequate, complete, and useable instructional materials."

The guidance document addresses only "instructional material." In some cases physical devices, such as cables, jigs, test equipment, and special tools, must be used to ensure compliance. The guidance document should address this issue by requiring OEM's to provide, at a reasonable cost of duplication and manufacture, those physical items and tools specifically fabricated by and for the OEM, required to perform all aspects of AIAT as defined.

The guidance document does not specifically prohibit the OEM from attaching prerequisites and stipulations to the provision of AIAT information. A similar requirement for documentation has been in force for laser equipment for over a decade (21 CFR 1040). OEM's of laser equipment have for years insisted they would provide all required documentation to anyone, provided the requestor attend the OEM's service school. While the documentation was always free, the cost of the service school was invariably several thousand dollars. Throughout this period FDA declined to formally address this issue while zealously requiring distribution of the information. Finally, in March of 1999, FDA published proposed changes to the laser performance standards (available at: <http://www.fda.gov/ohrms/dockets/98fr/032499c.pdf>) with this explanation contained in the supplementary information section:

"...FDA has recently received inquiries, suggestions, and one trade complaint concerning the interpretation of § 1040.10(h)(2)(ii), which requires manufacturers of laser products to provide adequate instructional information to servicers and others upon request."

"The correspondence FDA has received has reflected disagreement between manufacturers and independent servicers of laser products about whether the regulation authorizes manufacturers to interpret "adequate" to include training provided by the manufacturer. The agency believes that it

is appropriate for the manufacturer to decide, in the first instance, what constitutes “adequate” servicing instructions. If the agency learns, however, through the inspection of laser manufacturing

facilities or otherwise, that manufacturers are using the requirement of “adequate” as a pretext for making the provision of servicing instructions contingent upon costly or burdensome training, FDA will deem the manufacturer’s product to be noncompliant with the laser performance standard and will take appropriate regulatory action.”

While this excerpt clearly indicates the FDA’s ability to take appropriate steps preventing this type of activity, it must also be remembered that the office governing issues related to lasers is different from that which governs x-ray equipment. We believe and recommend FDA pursue use a similar process, with the same passion, to ensure consistency between departments and regulations and to demonstrate to the general public their efforts to preclude the training loophole from being used in this instance.

The guidance document discusses allowable expenses for determining the cost for AIAT information. With regard to instructional software, the document states the OEM may pass along the cost of licensing fees for third party software. This in and of itself is not objectionable if costs are reasonable, especially where the software may be available directly from the developer. It does however beg the question, “What does one do if the OEM enters into an exclusive marketing relationship with the software developer?” This is, in fact, what one OEM has done in the past with respect to the off-the-shelf operating system software for one of its imaging systems.

Finally, it appears the guidance document is not legally binding. The footnote for page 2 states:

“This document is intended to provide guidance. It represents the Agency’s current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.”

Within the last five years, the medical equipment service industry has undergone dramatic change. Many independent service organizations (ISO) have been acquired by the original equipment manufacturer (OEM). Others have simply ceased to exist due to equipment manufacture, design and service strategies of the OEMs.

Organizations such as National MD, InnoServ, Integrated Medical Systems, and Specialty Underwriters, to name only a few, held highly competitive positions within the medical equipment service industry. For the most part, these companies enjoyed reasonable market share in their areas of specialization and were considered to be quality, cost-effective service providers. Today, they no longer exist.

For the remaining ISOs, the battle for reasonable and economical access to AIAT documentation and software continues. Today, the ISO is the only viable and economical service alternative for healthcare institutions outside the OEM themselves.

If FDA fails to take a more active role in identifying, defining, and enforcing their requirements of the OEM as outlined in 21CFR, Section 10.20.30, the Independent Service Organization industry will continue to falter and eventually fail to remain a competitive, going concern in the medical equipment service industry. The absence of true competition will increase costs in this marketplace as it would in any market.

While a guidance document is an expeditious method of promulgating interpretations, without the force of law, the entire effort can quickly become null and void. FDA should take steps to ensure all interested parties are informed of the guidance document. Perhaps FDA can and will follow up with punitive actions against any parties not willing to accept this guidance. In light of FDA's history in the preceding years, however, there is ample room for suspicion that, in spite of FDA's guidance and best intent, we will soon again witness flagrant violation of the established regulations, the guidance document notwithstanding.

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